Reference number(s)
2374-A

SPECIALTY GUIDELINE MANAGEMENT

VENCLEXTA (venetoclax)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Venclexta is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), with or without 17p deletion, who have received at least one prior therapy.
2. Venclexta is indicated in combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

B. Compendial Uses
1. Mantle cell lymphoma
2. In combination with rituximab for relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in patients who have indications for treatment

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)
Authorization of 12 months may be granted for treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) when the member has received at least one prior therapy.

B. Newly-diagnosed Acute Myeloid Leukemia (AML)
Authorization of 12 months may be granted for treatment of newly-diagnosed acute myeloid leukemia (AML) when any of the following criteria is met:
1. The member is 75 years of age or older.
2. The member has comorbidities that preclude treatment with intensive induction chemotherapy.

C. Mantle Cell Lymphoma
Authorization of 12 months may be granted for treatment of mantle cell lymphoma.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

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1. Venclexta® [package insert]. North Chicago, IL: AbbVie Inc.; November 2018.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed September 04, 2018.
3. The NCCN Clinical Practice Guidelines in Oncology® Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (Version 1.2019) © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed September 17, 2018.
4. The NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas (Version 4.2018) © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed September 17, 2018.